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February 23, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20857

RE: Docket 99D-5435 (Photosafety Testing)

Dear Sirs:

In the draft guidance document on Photosafety Testing, you write that "The nonimmunologic photosensitivity response in a biologic system is directly related both to the light energy absorbed in the action spectrum and to the amount of compound (drug) present in the irradiated tissue." Further, in your decision tree A1, you indicate that if the topically applied formulation absorbs UVA, UVB, or visible radiation, and persists in the eye or skin or affects eye or sun-exposed skin, then photosensitivity testing should be conducted. In your decision tree A2, you indicate that if the topically applied formulation absorbs UVA, UVB, or visible radiation, and the formulation has not been previously tested, then photosensitivity testing should be conducted.

While photosensitivity testing is an important aspect in the overall risk assessment of a product, needless photosensitivity testing should be avoided. The guidance document states that "Drug products that do not absorb in this range (290-700 nm) will not be photoactivated (Box 1), and thus cannot be direct photosensitizers (Box 2). I find this insufficient guidance.

First, formulations that do not absorb in the UVB (280-320 nm) range need not be tested for photosafety in the UVB range because UVB-induced photosensitivity can not occur. Second, formulations that do not absorb UVB or UVA (320-400 nm) need not be tested for photosafety in the UVB range nor in the UVA range because neither UVB-induced nor UVA-induced photosensitivity can occur.

I have witnessed too many clinical situations in which formulations absorbing only in the visible range were tested for UVB photosensitivity or UVA photosensitivity. Such needless and expensive testing can be avoided with additional guidance.

Sincerely,

Michael Caswell, Ph.D.

99D-5435

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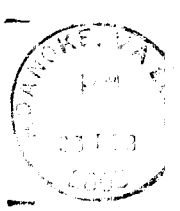

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